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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,357	03/25/2004	John E. Uschold	12013/50601	5454

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EXAMINER	
AHMED, AAMER S	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,357	USCHOLD, JOHN E.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

Claim 2 is objected to because of the following informalities: "the second surface is indented towards the second surface" is unclear; it is assumed that the claim is supposed to read, "the second surface is indented towards the first surface". Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Alchas U.S. Patent number 4,537,593. Alchas ('593) discloses a needle 20 comprising a shaft 26 having a distal end 31 defining a distal opening 35 and having a longitudinal axis extending through the distal opening, the distal opening 35 having a projected area that is smaller than a cross-sectional area of a section of the shaft 26 proximal to the distal end of the shaft 26; the needle 20 comprises opposing first and second surfaces, see figure 1 and the second surface is indented towards the first surface, see figure 1. Moreover Alchas ('593) describes that the distal end of the shaft 26 comprises at least one port 36 on it's side, the distal end terminates in a curvilinear distal tip 31 and the distal end of the shaft 26 is tapered, and the needle 20 being on the distal end of a syringe 117 see figures 1, 2 and 14.

Claims 1 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaslow U.S. Patent Number 4,753,641. Vaslow ('641) discloses a needle 12 comprising a shaft 1 having a distal end 20 defining a distal opening 8 and having a longitudinal axis 18 extending through the distal opening, the distal opening 8 having a projected area that is smaller than a cross-sectional area of a section of the shaft 1 proximal to the distal end of the shaft 1; wherein the distal end comprises opposing first 11 and second 5 extensions, which are angled towards each other and the second extension 5 is longer than the first 11 in a direction parallel to the longitudinal axis 18 of the shaft 1 and these extensions 5 and 11 mutually define at least one opening 8 offset from the longitudinal axis 18 of the shaft 1. Furthermore, Vaslow ('641) discloses that the at least one opening 8 is a pair of openings 8, see figure 3 and the extensions 5 and 11 each terminate in beveled distal tips, see figure 1.

Claims 1, 11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman U.S. Patent Number 6,346,099. Altman ('099) discloses a needle 312 comprising a shaft 328 having a distal end 316 defining a distal opening Col 5. Line 55 and having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft 328 proximal to the distal end of the shaft 328, see figure 3. In addition, Altman ('099) discloses that the needle 312 is on the distal portion of a catheter 5. Moreover Altman ('099) teaches a method of delivering a therapeutic agent to a target site of a body comprising providing a drug delivery device 306 containing a therapeutic agent and comprising the needle 312 of claim 1 at a distal portion thereof; and delivering the

therapeutic agent through the needle to a target site of a body Col. 3 line 18, wherein the drug delivery device is a catheter 5, the target site is the heart Col. 3 line 29, the method comprising of directly delivering the therapeutic agent to the target site Col. 3 line 22.

Claims 1 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Luther et al U.S. Patent Number 5,873,864. Luther et al ('864) method of accessing a drug delivery port comprising: providing a drug delivery device 10 comprising the needle 12 of claim 1 comprising a shaft 26 having a distal end 84 defining a distal opening 48 and having a longitudinal axis extending through the distal opening 48, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft 26 proximal to the distal end of the shaft 26 at a distal portion thereof; and inserting the needle 12 of the drug delivery device 10 into a drug delivery port 32 to access the drug delivery port, and wherein accessing the drug delivery port 32 comprising introducing a therapeutic agent through the needle 12 into the drug delivery port 32 comprising a septum 68 and the needle pierces 12 the septum 68 to access the port, and wherein the drug delivery device is a catheter 30 . Col. 4 line 23. and figures 1-4.

Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross U.S. Patent Number 5,843,048. Gross describes the needle 18 of claim 1, comprising a shaft 12 having a distal end 14 defining a distal opening 34 and having a longitudinal axis extending through the distal opening 34, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft 12

proximal to the distal end of the shaft 12; a method of delivering a therapeutic agent to a spinal column comprising: providing a drug delivery device 22 containing a therapeutic agent and comprising the needle of claim 1 at a distal portion thereof; and introducing the therapeutic agent through the needle into a spinal column Col. 7 line 2.

Claims 1, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al U.S. Patent Number 5,817,052. Johnson et al ('052) describes a needle 30, comprising a shaft 31 having a distal end 50 defining a distal opening 52 and having a longitudinal axis extending through the distal opening 52, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft 31 proximal to the distal end of the shaft 31. Johnson et al ('052) further describes a method of collecting a fluid sample from a body comprising: providing a drug delivery device comprising the needle 30 at a distal portion thereof, inserting the needle 30 into a fluid containment site of a body; and creating a vacuum in the drug delivery device to collect a fluid sample from the fluid containment site of the body, Col. 19 line 40 and the fluid sample consists of blood, Col. 19 line 7.

Claims 24, 25, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman U.S. Patent Number 6,346,099. Altman ('099) describes a method of directly delivering a therapeutic agent to a target site of a body comprising: providing a drug delivery device comprising a Huber needle 312 at a distal portion thereof; positioning the needle adjacent to the target site; and directly delivering the therapeutic agent through the Huber needle to the target site, wherein the target site is not a spinal cord, but the heart Col. 3 lines 22 and 33.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Dinsmore et al US Publication Number 20040191225 A1. Dinsmore ('225) describes a method of directly delivering a therapeutic agent to a target site of a body comprising providing a drug delivery device comprising a pencil-point needle, figure 1 at a distal portion thereof; positioning the needle adjacent to the target site; and directly delivering the therapeutic agent through the pencil-point needle to the target site, wherein the target site is the heart myocardium page 6 paragraph 47.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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US 20030139727 A1 Angel, Aimee B. et al.

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US 20030028146 A1 Aves, Teodulo

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US 5634913 A Stinger; Florence

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US 2904045 A THOMAS OWINGS

US 4689040 A Thompson; Robert J.

US 5312422 A Van der AA; Bartholomeus W. J. et al.

US 5573519 A Zohmann; Walter A.